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10/780,267

02/17/2004

Donald Lynn Bissett

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27752 7590 10/05/2007
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EXAMINER

ISSAC, ROY P

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/780,267

Applicant(s)

BISSETT, DONALD LYNN

Examiner

Roy P. Issac

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 6-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 21-26, 28-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This Office Action is in response to Applicant's amendment/ remarks/ response filed 7/18/2007, wherein claim 27 has been cancelled and claims 1, 21, 23 and 25 have been amended.

Rejections Withdrawn

In view of the cancellation of claim 27, all rejections made with respect to claim 27 in the previous office action are withdrawn.

The rejection under 35 USC 112 second paragraph, with respect to claims 1-5 and 21-29 in regards to the term "derivative" is withdrawn since the term is deleted from claims 1 and 26.

The rejection under 35 USC 102(b), with respect to claims 1-5 in is withdrawn since the deletion of the term "retinoid" overcomes the rejection.

The following are new grounds of rejection necessitated by applicants amendments:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 21, 23-24, 26 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissett et. al. (U.S. Patent No. 6,284,802; PTO-892).

Bissett et. al. discloses the use of vitamin B3 compounds in skin care compositions. (Column 33, claim 3). Example 1 discloses a composition with 2% niacinamide, a vitamin B3 compound. (Column 30, lines 1-5; Column 16-17, section titled "Vitamin B3 compounds"). Water, glycerin and silicone fluids are disclosed in emulsions and are considered carriers. (Example 2). Hexamidine is disclosed as useful as an antimicrobial adduct. (Column 23, line 45-55). Bissett further discloses the use of anti-acne actives, peptides, scavengers and sunscreen additives. (Column 34, claim 6; See Column 16, section titled "Desquamation agents"; Column 18, titled "peptides"): Bissett further discloses ascorbyl glucosamine as an additive. (Column 15, lines 65-68). Glucosamine and panthenol are disclosed as a conditioning agents. (Column 25, lines 50-Column 26, line 5; Column 33, claim 4). Tocopherol acetate is disclosed as an anti-oxidant additive. (Column 19, lines 1-36).

Bissett does not exemplify a composition comprising hexamidine

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a skin care composition comprising hexamidine, and vitamin B3 and additional ingredients such as peptides, additives claimed in claim 3, and tocopherol acetate since all ingredients are well known for their use in skin care preparations and useful for compositions for skin care as disclosed in Bissett et. al. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

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Therefore, one of ordinary skill in the art would have reasonably expected that a composition comprising hexamidine in combination with other cosmetic/ skin care actives would have resulted in beneficial effects as a skin care composition.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

The following are new or modified rejections necessitated by Applicant's amendment filed 7/18/2007, wherein the limitations in pending claims 1, 21, 23 and 25 as amended now have been changed. The limitations in the amended claims have been changed and the breadth and scope of those claims have been changed. Therefore, rejections from the previous Office Action, mailed 4/19/2007, have been modified and are listed below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, and 4-16 of copending Application No. 10/152,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '924 application is directed to an article comprising a skin care composition comprising hexamidine, niacinamide (vitamin B3) and a carrier. The claims herein are directed to a composition comprising hexamidine, vitamin B3 and a carrier. Thus, claims 1-3 are deemed anticipated by claims 1-2 and 4-16 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments/ response filed 7/18/2007 have been fully considered but they are not persuasive. Applicants submit that they would file a terminal disclaimer upon notice of allowable subject matter. However, the double patenting rejection will be maintained until terminal disclaimers are received. (MPEP 804(I)(B)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 23, 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. (Of record) in view of Flick et. al. (Cosmetic Additives – An industrial Guide, Pages 647-648, 652; Of record), Gensler et. al. (Nutrition and Cancer, 29(2), 157-162; Of record) and Oblong et.al. (JP2002212053, Abstract; PTO-892).

Jensen et. al. discloses compositions comprising hexamidine (0-1%), and carriers including water, seed oil and vegetable oil. The presence of water, fruit juice, glyceryl stearate, seed oil, vegetable oil and PEG-40 stearate is expected to form an emulsion in the form of a water-in-oil or oil-in-water or a combination of both.

Furthermore, Jensen et. al. discloses the use of panthenol in a skin care composition.

Jensen et. al. does not expressly disclose a composition comprising vitamin B3 or panthenol in combination with a hexamidine compound and a carrier. (Column 11, Example 2, line 53-64). Jensen et. al. further discloses the use of tocopheryl acetate (Column 11, Example 2, line 58-60, Example 4, lines 43, Example 1).

Flick et. al. in his cosmetic handbook discloses that panthenol is used in skin care products as a quick deep penetrating moisturizer, that aids in tissue repair and

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promotes normal keratinization. (Cosmetic Additives – An Industrial Guide, Page 648, Paragraph titled “Role in skin care products”). Flick et. al. further discloses commercial sources of panthenol compounds. (Page 647). Flick et. al. further discloses commercial sources of various forms of vitamin E including α -tocopherol acetate. (Page 652) As such, panthenol and α -tocopherol acetate are considered as ingredients well known by one of ordinary skill in the arts in the cosmetic, pharmaceutical and skin care industry.

Gensler HL et. al. discloses that topical nicotinamide prevents the systemic immunosuppression and skin tumorigenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that immunoenhancement by nicotinamide results in prevention of phtocarcinogenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that α -tocopherol can also contribute to inhibition of photoimmunosuppression and photocarcinogenesis. (Page 161, Column 2, second paragraph). One or ordinary skill in the art would recognize protecting against UVB as a beneficial in a skin care composition.

Oblong et. al. discloses that vitamin B3 compounds can have beneficial effects such as improving tactile discontinuities of the skin. Oblong discloses the use of 2-5% niacinamide. (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, vitamin B3, panthenol, α -tocopherol acetate and a carrier because Jensen et. al. discloses skin care compositions comprising α -tocopherol acetate, hexamidine and discloses

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panthenol in skin care compositions and Flick et. al. discloses panthenol and α -tocopherol acetate as commercially available cosmetic additives and Gensler et. al. discloses that topical application of niacinamide and α -tocopherol can contribute to protection against UVB rays and Oblong et. al. discloses the beneficial effects of niacinamide such as regulating visible and tactile discontinuities of the skin. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All ingredients in the instant composition are well known in the prior art for use in skin care compositions with various beneficial effects. The combination of said ingredients results in a topical combination with expected results. Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and α -tocopherol in skin care compositions would have had beneficial effects such as moisturizing, maintenance of keratinization, protection against wrinkles and protection from UVB rays.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 7/18/2007 have been fully considered but they are not persuasive. Applicants argue that, the Gensler reference only teaches the use of

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nicotinamide protects against UVB radiation induced photoimmunosuppression, and does not disclose combining nicotinamide with other actives. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore applicants argue that there is no reason for one of ordinary skill in the art to combine Gensler's teaching of the efficacy of nicotinamide against UVB radiation in making a skin care composition. This argument was found unpersuasive since protecting against UVB radiation is considered a use one of ordinary skill in the art would recognize as beneficial in a skin care composition. Applicants further argue that the concentration of nicotinamide used in Gensler et. al. does not fall into the 0.01 to 10% for additional skin care actives claimed herein. Applicant assert that, "The only nicotinamide containing composition disclosed in Gensler is 40 μ mol of nicotinamide and 200 μ mol of acetone." (Emphasis added). However, this statement is inaccurate. Gensler discloses 40 μ mol of nicotinamide in 200 μ l of acetone. (See Page 157, column 2, last paragraph). 40 μ mol of nicotinamide is calculated to be 4.88micrograms and 200 μ l of acetone is calculated to be 148milligrams, resulting in a 0.00309% composition falling well within the range claimed herein. As such, the rejection under 103(a) is still deemed proper and is adhered to.

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Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Gensler et. al. (Nutrition and Cancer, 29(2), 157-162; Of record), Mammone et. al. (WO 00/67722; Of record) and Oblong et. al. (JP2002212053, Abstract; PTO-892).

The disclosure of Jensen et. al. is disclosed above.

Jensen et. al. does not expressly disclose the use of vitamin B3 compounds, in particular niacinamide or the use of N-acetyl glucosamine in skin care compositions.

The disclosure of Gensler et. al. is discussed above.

Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions used for exfoliation and moisturization. (Abstract, Page 2, lines 14-17).

The disclosure of Oblong is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, N-acetyl glucosamine, niacinamide and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine and Gensler et. al. discloses that topical application of niacinamide can contribute to inhibition of photoimmunosuppression and photocarcinogenesis and Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions as an exfoliant and Oblong discloses the use of niacinamide against tactile discontinuities of the skin. All the claimed steps herein are known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the

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invention. All ingredients in the instant composition are well known in the prior art for use in skin care compositions with various beneficial effects. The combination of said ingredients results in a topical combination with expected results. Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and α -tocopherol in skin care compositions would have had beneficial effects such as moisturizing, maintenance of keratinization, protection against wrinkles and protection from UVB rays.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 7/18/2007 have been fully considered but they are not persuasive. Applicants argue that, the Gensler reference only teaches the use of nicotinamide protects against UVB radiation induced photoimmunosuppression, and does not disclose combining nicotinamide with other actives. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore applicants argue that there is no reason for one of ordinary skill in the art to combine Gensler's teaching of the efficacy of nicotinamide against UVB radiation in forming a skin care composition. This argument was found unpersuasive since protecting against UVB radiation is

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considered a use one of ordinary skill in the art would recognize as beneficial in a skin care composition. Applicants further argue that the concentration of nicotinamide used in Gensler et. al. does not fall into the 0.01 to 10% for additional skin care actives claimed herein. Applicant assert that, "The only nicotinamide containing composition disclosed in Gensler is 40 μ mol of nicotinamide and 200 μ mol of acetone." (Emphasis added). However, this statement is inaccurate. Gensler discloses 40 μ mol of nicotinamide in 200 μ l of acetone. (See Page 157, column 2, last paragraph). 40 μ mol of nicotinamide is calculated to be 4.88micrograms and 200 μ l of acetone is calculated to be 148milligrams, resulting in a 0.00309% composition falling well within the range claimed herein. As such, the rejection under 103(a) is still deemed proper and is adhered to.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Castiel et. al. (US 2003/0176366 A1, PTO-892), (WO 00/67722; Of record) and Oblong et. al. (JP2002212053, Abstract; PTO-892).

The instant application is a CIP of 10/379,252, filed 03/04/2003. However, the '252 application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the instant new claim 25 of this application for CIP since the '252 application do not disclose the particular composition comprising ascorbyl

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glucoside recited in claim 25. Therefore, the filing date of claim 25 is deemed to be the filing date of the instant application, 02/17/2004.

The disclosure of Jensen et. al. is discussed above

Jensen et. al. does not expressly disclose the use of ascorbyl glucoside in skin care compositions or a 0.01 to 10% of a vitamin B3 compound.

Castiel et. al. discloses that ascorbic acid compounds, in particular ascorbyl glucoside increases epidermal lipogenesis. (Column 2, Paragraphs 22-25, Example 1, Paragraphs 57-62; Page 4, Column 1, Table) Castiel further exemplifies cosmetic compositions comprising ascorbyl glucoside (Page 4, Column 2, Example 3).

The disclosure of Oblong is discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, a retinoid, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, carriers and a retinoid and Castiel et. al. discloses the use of ascorbyl glucoside in skin care compositions to increase epidermal lipogenesis.

One of ordinary skill in the art would have been motivated to make a skin care composition comprising hexamidine, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, a retinoid, and a carrier and Castiel et. al. discloses that the use of ascorbyl glucoside in skin care compositions increases epidermal lipogenesis.

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Therefore, one of ordinary skill in the art would have reasonably expected that the use ascorbyl glucoside in a skin care composition comprising hexamidine, a retinoid and a carrier would result in substantially similar or improved skin care composition.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Response to Arguments

Applicant's arguments filed 7/18/2007 have been fully considered but they are not persuasive. Applicants argue that there is no reason for one of ordinary skill in the art to combine Gensler's teaching of the efficacy of nicotinamide against UVB radiation in forming a skin care composition. This argument was found unpersuasive since protecting skin against UVB radiation is considered a use one of ordinary skill in the art would recognize as beneficial in a skin care composition. Applicants further argue that the concentration of nicotinamide used in Gensler et. al. does not fall into the 0.01 to 10% for additional skin care actives claimed herein. Applicant assert that, "The only nicotinamide containing composition disclosed in Gensler is 40 μ mol of nicotinamide and 200 μ mol of acetone." (Emphasis added). However, this statement is inaccurate. Gensler discloses 40 μ mol of nicotinamide in 200 μ l of acetone. (See Page 157, column 2, last paragraph). 40 μ mol of nicotinamide is calculated to be 4.88micrograms and 200 μ l of acetone is calculated to be 148milligrams, resulting in a 0.00309% composition

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falling well within the range claimed herein. As such, the rejection under 103(a) is still deemed proper and is adhered to.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Roy P. Issac
Patent Examiner
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S. Anna Jiang, Ph.D.
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